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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,843	03/30/2001	Samir Kumar Brahmachari	Q63915	7045
7590	04/04/2005		EXAMINER	
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20037-3213			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,843	BRAHMACHARI ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 20-24,26-30,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20-24,26-30,32 and 33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Applicant's amendments and remarks, filed 2/18/05, are acknowledged. Amended claims 20, 30, and 32 are acknowledged.

Applicant's arguments, filed 2/18/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 20-24, 26-30, and 32-33 are herein under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-24 and 26-28 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

This rejection is maintained and reiterated for reasons of record.

As written, claims 20-24 and 26-28 encompass a method performed on a computer that appears to lack any physical result performed outside of a computer.

As stated in MPEP § 2106, (IV)(B)(2)(b), to be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(B)(2)(b)(i)), or (B) be

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limited to a practical application within the technological arts (discussed in MPEP § 2106

(IV)(B)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(B)(2)(b)(i), the independent physical acts may be post- or pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. *Schrader*, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval *Arrhythmia*, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; *Abele*, 684 F.2d at 909, 214 USPQ at 688; *In re Taner*, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(B)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 20-24 and 26-28 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 20-24 and 26-28 appear to lack a practical application as stated in MPEP § 2106 IV.B.2.b.ii. Regarding practical application, the MPEP § 2106 (IV)(B)(2)(b)(ii) states the following example:

A computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

Comparing the above scenario to claims 20-24 and 26-28, the claimed method that merely identifies an anti-infective is comparable to the nonstatutory example given above as it does not appear to have a valid practical application applied to the identification. The claimed invention falls more into the example of noise analysis. In this example, it is not until the noise is filtered that a practical application is clearly expressed. In the instant invention, clarification in the claims of what practical application the identification provides would nullify this rejection.

Claims 20-24 and 26-28 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing. This rejection is necessitated by amendment.

As stated in MPEP § 2106, (IV)(B)(1), if the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not

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being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59.

Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 20-24 and 26-28 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. This rejection is necessitated by amendment.

Applicants state that courts have recognized computer programs and mathematical algorithms and/or formulas as patentable subject matter when applied in a useful way. This statement is found unconvincing regarding the instant invention, because while the MPEP does cite a practical application of the invention as being a safe harbor for 35 USC 101, the practical application is interpreted to involve a physical step or a representation of a physical step which does not appear to be present in the instant claims. Applicants mention “useful” algorithms (Arrhythmia Research Technology, Inc. v. Corazonix) are patentable. To be statutory, Applicants are again directed to the the MPEP § 2106 (IV)(B)(2)(b)(ii) states the following example:

A computer process that simply calculates a mathematical algorithm that models noise is

nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

In this example, a practical application is achieved in the invention by filtering noise. This filtering of noise represents a physical step or representation of a physical step that demonstrates a practical application. In the instant invention, the phrase “identifying a candidate protein useful as an anti-infective” does not make the claimed invention statutory, because no physical step or representation of a physical step is clearly set forth in the claims. There is no concrete, tangible, and useful result present. Applicants state they have amended in a selecting step of an outlier protein for further testing to demonstrate a practical application in the method steps. This statement is found unpersuasive as this selection may still occur on the computer. Furthermore, step (e) can also be performed within the computer without generating a physical step outside of the computer. Without an actual physical step (i.e. physical laboratory testing or displaying tests results [representing concrete and tangible results]) or representation of a physical step, the claimed invention appears to be nonstatutory subject matter. Applicants state applying the algorithm to protein sequences is statutory and useful. This statement is found unpersuasive, because even if the result is useful, it is still not concrete and tangible which could be remedied by stating a physical step or a physical representation of a physical step. Applicants state the law does not change from patent application to patent application. It is noted that every patent application is examined under its own fact pattern.

Claim Rejections - 35 USC § 11, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained and reiterated for reasons of record.

NEW MATTER

The comparison step has been omitted in currently amended 20. Applicants state in the Remarks section, page 6, filed 9/14/04, that the recitation of "(d) comparing said outlier proteins to known proteins to identify a unique outlier protein" is removed as it is not an essential to the invention. This is found unpersuasive as the specification (page 8) states the present invention comprises steps i) through vi) which includes a matching step and selecting step assumed to be represented by the now omitted comparison step. This omission presents a conflict with what the specification describes as the present invention. Because the omission of the comparison step (d) does not appear to have adequate written support in the specification, claims, or drawings as originally filed, this omission is considered to be NEW MATTER. Claims 21-24, 26-30, and 32-33 are also rejected due to their dependency from claim 20.

Applicants cite Example 5 as an example where the comparison step did not occur. This statement is found unpersuasive as Example 5 mentions the identification of 7 outlier sequences, then states their correspondence to glycine rich protein PE_PGRS of *M. tuberculosis* (representing a comparison to a known protein) as well as the mention of these “unique outlier protein sequences” which still entails the limitations of comparison step (d) of instant claim 20, filed 2/2/04. Applicants cite Example 6 as an example where the comparison step did not occur. This statement is also found unpersuasive as a comparison step of some type was performed in order to come up with the information in Table 1 and then Example 6 mentions the “unique outlier protein sequences” which demonstrates that comparisons were performed in order to denote the name “unique” to these sequences. Applicants cite Example 7; but it is noted that this example also mentions the “unique outlier protein sequences” which demonstrates that comparisons were performed in order to denote the name “unique” to these sequences. These comparisons all represent step (d), filed 2/2/04, that was omitted and is considered to be essential to the invention. Therefore, the NEW MATTER rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 29, 2005


ARDIN H. MARSCHEL
PRIMARY EXAMINER